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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,736	02/20/2002	Justin R. Fallon	BURF-P02-006	2816
28120	7590	09/20/2004	EXAMINER	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			CHERNYSHEV, OLGA N	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,736

Applicant(s)

FALLON ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-38 is/are pending in the application.
- 4a) Of the above claim(s) 17-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-16 and 32-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20/2/2 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/24/2; 11/26/2.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group I in the reply filed on July 13, 2004 is acknowledged. The traversal is on the ground(s) that Group I and Group VIII share common features that would facilitate searching these groups at once, and, further, that Groups IV-IX each contain only one claim and, therefore, examination of all groups would not impose a substantial additional burden on the Examiner (bottom at page 5 of the Response). This is not found persuasive for the following reasons. The invention of Group I is directed to a method for activating a postsynaptic membrane by contacting a cell membrane with a biglycan. The search for this invention and for the invention of Group VIII, for example, is not coextensive. Such search would include sequence search as well as search of technical literature. Prior to the search of sequence databases related to biglycan molecule of SEQ ID NO: 9 there may be patent and non-patent literature devoted solely to interaction between MuSK and biglycan, and such art is not coextensive in scope with art describing administration of biglycan to a cell *in vivo* or *in vitro*, for example. Furthermore, the search for the different inventive concepts of Groups I and Group VIII, as well as other Groups, would impose a serious search burden since a search for the art disclosing administration of biglycan to a cell would not be used to determine the patentability of a method for identifying a modulator of interaction between biglycan and MusK.

The requirement is still deemed proper and is therefore made FINAL.

Claims 17-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

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Applicant timely traversed the restriction (election) requirement in the reply filed on July 13, 2004.

Claims 13-16 and 32-38 are under examination in the instant office action.

Drawings

2. Figures 3A, 3B, 3C, 8A, 8B and 8C of the instant application are presented in separate panels. Applicant is reminded that once the drawings are changed to meet the separate numbering requirement in accordance with 37 C.F.R. § 1.84(u) (1), the specification should be amended to change the Brief Description of the Drawings and the rest of the specification to refer to each Figure accordingly, such as, for example, in description of Figures 5A-5C.

3. Also, there appears to be no Figure 3D in the instant specification, as filed. Therefore, reference to Figure 3D on page 9 of the instant specification appears to be an error. Clarification is required.

Specification

4. Claim 32 is not in compliance with the requirements for Sequence Identifiers (see MPEP 2422.03). The appropriate format for sequence identifiers is SEQ ID NO: X, wherein "X" is the sequence number. Appropriate correction is required.

Claim Objections

5. Claims 32-38 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 32 depends from claim

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13, which is limited to a method reciting a biglycan therapeutic, while claim 32 encompasses a method reciting a portion of a biglycan therapeutic, which, by the broadest reasonable interpretation, can be limited to one amino acid. Therefore, claim 32 and depending claims 33-38 can be infringed by a method reciting administration of an amino acid, which would not infringe claim 13. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant should note the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything, which would not also infringe the basic claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 14-15 and 32-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Claims 14 and 15 are vague and indefinite in so far as they employ the term "MuSK" as a limitation. This term appears to be an acronym or a novel term, and without a reference to a full name or to a precise amino acid sequence identified by a proper SEQ ID NO: one cannot determine the metes and bounds of "MuSK". Moreover, because the instant specification does not identify that property or combination of properties which is unique to and, therefore,

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definitive of a “MuSK”, an artisan cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

8. Claim 32 is vague and ambiguous for recitation “or a portion thereof”. It is not clear and cannot be determined from the claim or the instant specification if “a portion” refers to a polypeptide having 90% identity to SEQ ID NO: 9 or to the biglycan, such portion which, by the broadest reasonable interpretation, could be limited to one amino acid. Clarification is required.

9. Claims 33-38 are indefinite for being dependent from indefinite claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 13-16 and 32-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruoslahti et al., US Patent No. 5,654,270, 1997.

Claims 13-16 and 32-38 are directed to a method for activating a postsynaptic membrane of a cell by contacting the cell with a biglycan, which is 90% identical to amino acids 38-365 of SEQ ID NO: 9. Ruoslahti et al. disclose use of proteoglycans, which include biglycan (column 2, lines 9-26) of SEQ ID NO: 3, which is 99.3% identical to biglycan of SEQ ID NO: 9 of the instant invention (see copies of sequence alignments attached to the instant office action) to inhibit an activity of a cell regulatory factor (see abstract, for example). Proteoglycans of

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Ruoslahti et al. carry one or more glycosaminoglycan chains (see column 1, lines 21-22) and comprise include leucine-rich repeat (column 3, lines 11-12). Ruoslahti et al. describe using proteoglycans in scarring studies (Example VI, columns 19 and 20), wherein decorin, a molecule homologous to biglycan (bottom at column 7 continuing to column 8), was added to a wound cut down to the skeletal musculature, thus, providing a contact with a membrane of a muscle cell.

The results of the same procedure are reasonably expected to be the same. The discovery of an inherent property of a prior art process can not serve as a basis for patenting that process. See *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A U.S. patent to Dart disclosed inoculation using *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating.).

Therefore, one would reasonably conclude that contacting proteoglycans with a muscle cell, as described by Ruoslahti et al., lead to binding to MuSK, potentiated agrin-induced phosphorylation of MuSK and unregulated utroplin levels, absent evidence to the contrary.

Conclusion

11. No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.


OLGA N. CHERNYSHEV, PH.D.
PATENT EXAMINER